



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

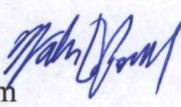
OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

September 11, 2007

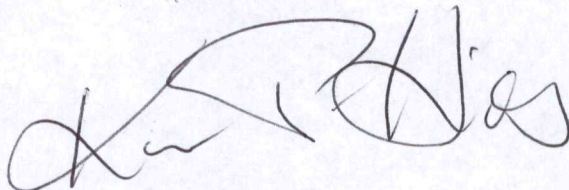
MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 84368-R  
DP Barcode: D340584

To: Adam Heyward, PM 34/ Lisa McKelvin  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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Through: Karen Hicks, Team Leader  
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Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Mandala Technologies, LLC

ACTIVE INGREDIENT:	<u>% by wt.</u>
Ethanol	29.4

BACKGROUND

In support of product registration for DETOX, EPA File Symbol 84368-R, the applicant has requested data waivers for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, skin irritation, and skin sensitization. In each waiver rationale, the applicant refers to the very low acute effects of ethanol (as indicated in the public literature and the Agency's



Aliphatic Alcohols Reregistration Eligibility Decision [RED] document) and of the other formulation components that are present at significant concentration.

### RECOMMENDATION

The eye irritation data waiver request is unacceptable. It is not known what effect the surfactant or the pH of the product will have on acute eye effects (though corrosiveness is not expected).

The other five acute toxicity data requirements can be waived. However, skin irritation may be modestly affected by the presence of the surfactant and the pH adjustor, so the product is placed in Toxicity Category III for skin irritation.

#### Recommended acute toxicity profile:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity		IV	Waived
Acute Inhalation Toxicity		IV	Waived
Primary Eye Irritation		?	Required
Primary Skin Irritation		III	Waived
Dermal Sensitization		Non-sensitizer	Waived

#### Product labeling:

Based on the above acute toxicity profile and the Agency's *Label Review Manual*, the signal word (*CAUTION* or other, depending on eye irritation) is required on the front/main panel. The *Precautionary Statements* heading and the *Hazard to Humans and Domestic Animals* subheading are also required, followed by the statement: *Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.*

A First Aid section is required. (If it is not placed on the front/main panel, a referral statement such as "see side/back panel for first aid" should appear on the front panel in close proximity to the Signal Word.) The section should include this statement:

*If on skin:*

- Take off contaminated clothing.*
- Rinse skin immediately with plenty of water for 15-20 minutes.*
- Call a poison control center or doctor for treatment advice.*



General information to include near the first aid statement:

*Have the product container or label with you when calling a poison control center or doctor or going for treatment.*

Any further labeling comments regarding the human-hazard precautionary and first aid statements will be completed after the eye irritation data requirement is met.